APR 2 2 2002

K020184/S1
page 1 of 2

# 510(k) Summary for HomMed Central Station

| | |
|---|---|
| Submitter: | HomMed, LLC |
| Address: | 19275 West Capital Drive, Suite 200<br>Brookfield, Wisconsin 53045 |
| Corporate Contact: | Herschel Peddicord, President, HomMed, LLC |
| Telephone: | Ph: (262) 783-5440<br>Fax: (262) 783-5441 |
| Submission Contact: | Tommie J. Morgan Ph.D., President<br>Morgan Consultants, Inc.<br>2018 North Durham<br>Houston, Texas 77008<br>Ph: (713) 880-5111<br>Fax: (713) 880-3494 |
| Prepared: | December 15, 2001 |
| Proprietary Name: | HomMed Central Station |
| Common/Classification Name: | Cardiovascular |
| Predicate Device: | HomMed Observer, Model I |
| New Device Description: | HomMed Central Station |

Intended Use:
The HomMed Central Station intended use is to retrospectively receive, display, evaluate, analyze and store certain monitored physiological parameters of patients when this data is acquired within healthcare and home environments. The Central Station is the accessory device used by the healthcare professional to display and evaluate the monitored patient data from the HomMed Sentry, Patient Monitor Systems and the healthcare professional is responsible for the interpretation of the monitored data made available by the Central Station. The data received from the Sentry and displayed by the Central Station will be utilized by healthcare professionals, (including physicians and/or physician supervised nurses), to retrospectively view patient physiological data. Physiological data, system alerts and patient data analysis will be available to the health care provider from Observer. The Central Station, a retrospective data view and analysis system is not intended for emergency use or real-time monitoring of data received from the HomMed Sentry Patient Monitors.

Performance Data:
The HomMed Central Station is a software system that operates on a commercially available PC system with the minimum performance specifications consistent with typical PC hardware and equipment specifications. The HomMed Central Station is a software system that is an accessory to the HomMed Sentry Patient Monitors. The software validation results demonstrated that the HomMed Central Station System was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding patient monitors.

## Compliance to Standards and Regulations:

### Safety

Medical Software Validation Standards

| | |
|---|---|
| EN 60601-1 | Medical Electrical Safety |
| IEC 601-1-2 | EMC Compliance |
| ISO 10993-5,10-11 | Biocompatibility |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2002

HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants, Inc.
2018 North Durham
Houston, TX 22008

Re: K020184
Trade Name: HomMed Central Station
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: April 2, 2002
Received: April 3, 2002

Dear Dr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K020184

***Device Name: HomMed Central Station***

## Indications for Use

The HomMed Central Station is intended to be used to retrospectively receive, display, evaluate, analyze and store certain monitored physiological parameters of patients within healthcare and home environments. The physiologic patient parameters available for retrospective display and evaluation include NIBP, pulse rate, SpO2, temperature and weight. The Central Station will be the device used by the healthcare professional to display and evaluate the monitored patient data, and the healthcare professional is responsible for the interpretation of the monitored data made available by the Observer. The Central Station data will be a utilized by the healthcare professional health including physicians and/or physician supervised nurses. Physiological data, system alerts and patient data analysis will be available to the health care provider from Central Station that may be considered as a retrospective data monitor system.

(PLEASE DO NOT WRITE BELOW THIS LINE - - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____Only_____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020184